UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456**
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS	**Judge Patti B. Saris**

REPLY MEMORANDUM OF ABBOTT LABORATORIES
IN SUPPORT OF ITS INDIVIDUAL MOTION TO DISMISS

I. ALL CLAIMS RELATING TO MULTIPLE-SOURCE DRUGS SHOULD BE DISMISSED FROM THIS CASE PURSUANT TO RULES 12(b)(6) AND 9(b)

All claims in the Complaint should be dismissed to the extent that they relate to Medicare reimbursement for multiple-source drugs. Although Abbott and Warrick raised this argument in their five-page individual briefs, plaintiffs declined to make any response whatsoever. The Court should deem the plaintiffs to have conceded the point, and rule accordingly.

In fact, plaintiffs cannot respond to Abbott's argument. As plaintiffs themselves explain in the Complaint, Medicare's reimbursement for multiple-source drugs is not based on the AWP of a single manufacturer. Instead, reimbursement for multiple-source drugs is based on "the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP." Compl. ¶ 148. *See* 42 C.F.R. § 405.517(c). In light of this regulatory scheme, plaintiffs cannot explain how Abbott could have "manipulated" reimbursement rates or "increased [its] market share" at the expense of its competitors, as alleged in the Complaint. *See, e.g.,* Compl. ¶¶ 3, 184, 191. This is particularly critical for Abbott, as at least fifteen of the seventeen Abbott products mentioned in the Complaint are multiple-source drugs. *See* Compl. ¶ 190.

The Medicare reimbursement methodology for multiple-source drugs is directly contradictory to plaintiffs' claims. Plaintiffs' legal theory, as described in the Complaint and in their brief, is founded on competition between manufacturers. In order to gain an advantage over competitors, drug companies allegedly raised the AWPs of their drugs to increase the profit to physicians who purchased and administered the drugs. As plaintiffs repeatedly contend, their case relies upon the following proposition: "[Manufacturers] inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients and their insurers. This, in turn, incentivizes the providers to sell and administer the drugs with the most

inflated AWPs, resulting in increased market share and profit." Compl. ¶ 3; Pl. Brief at 3 (quoting same). *See, e.g.,* Compl. ¶¶ 4, 6, 157-65, 171; Pl. Brief at 3, 4, 6-7, 31, 33, 35.

Under the reimbursement rules applicable to multiple-source drugs, however, the scheme alleged by plaintiffs cannot be executed. The following comparative hypotheticals illustrate the flaw in their theory of recovery as it applies to such drugs:

First, assume that two proprietary drugs are competing against each other. According to the Complaint and to Medicare rules, reimbursement is based separately on the AWP of each drug. Thus, plaintiffs allege, "manipulation" of one drug's AWP will result in competitive advantage over the other drug because providers will earn more profit. This is the paradigm on which plaintiffs base their claims.

Second, consider the same situation with competing multiple-source drugs. The competitive advantage and AWP "manipulation" described in the Complaint cannot occur. If, for example, five companies manufacture the drug, then the Medicare reimbursement rate will be based on the median (not average) AWP of these drugs. If the AWPs of the five manufacturers' formulations of the drug are $3, $5, $7, $8 and $50, then the reimbursement rate for all will be based on an AWP of $7. This is true even for the drug with a $50 AWP. If a manufacturer changes its individual AWP, that might affect the median AWP, but all drugs would be affected equally. That is, no manufacturer could gain a competitive advantage by raising its AWP, as all forms of the drug are *always* reimbursed at the *same rate*.

In short, multiple-source drugs have no place in this Complaint. Under the law that governs reimbursement for such drugs, the scheme alleged by plaintiffs could not have occurred. Pursuant to Rule 12(b)(6) and Rule 9(b), this Court should dismiss with prejudice all claims relating to the Medicare reimbursement of multiple-source drugs.

II. THE CLAIMS OF THE ERISA-PLAN PLAINTIFFS SHOULD BE DISMISSED

Plaintiffs have not explained their failure to comply with Rule 17. The unambiguous meaning of 29 U.S.C. § 1132(d) permits ERISA plans to sue or be sued in their own name only for claims brought under Title 19 of the United States Code. For other actions, Rule 17 requires that the plan trustees be named as the real parties in interest. In no case cited by plaintiffs did the court permit an ERISA plan to sue in its own name for a non-ERISA cause of action.

III. PLAINTIFF GELLER'S CLAIMS SHOULD BE DISMISSED

Plaintiffs fail to explain satisfactorily the Rule 9(b) deficiencies with respect to plaintiff Geller, the only individual plaintiff who even arguably alleged the use or payment of an Abbott-manufactured product: the multiple-source drug vancomycin. Plaintiffs do not point to any allegations in the Complaint or elsewhere that identify Abbott as the maker of the vancomycin received by Geller. They do not state when and how the drug was administered to her, or when she made a Medicare co-payment for it. Rather, plaintiffs argue only that Medicare *might* have paid for Geller's vancomycin after September 1, 1996 if it was administered intravenously. Significantly, however, plaintiffs do not allege that Geller received vancomycin in this manner. Geller should know these facts, but has chosen to remain silent. As such Geller's claims against Abbott should be dismissed for failure to allege fraud with particularity.

IV. PLAINTIFFS' OTHER ARGUMENTS ARE MERITLESS

Plaintiffs fail to respond adequately to the other arguments raised by individual defendants, including Abbott, regarding standing, Rule 9(b) and tolling of the statute of limitations. As to these arguments, Abbott relies on its opening briefs and on the individual replies filed by other defendants. Specifically as to Rule 9(b), however, Abbott notes that plaintiffs fail even to attempt to distinguish *United States ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999), which is directly on point.

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